111-1120.00-
patent Term

CERTIFICATION UNDER 37 C.F.R. 1.10

EM032271482958 — February 6, 1998

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I hereby certify that this paper, fee and documents referred to herein is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Asst. Commissioner for Patents, U.S. Patent and Trademark Office, Box Patent Ext., Washington, D.C. 20231.

Cederic Rodgers — Cederic Rodgers

Name of Person Mailing Application — (Signature of Person Mailing Application)

TRANSMITTAL OF APPLICATION FOR EXTENSION OF THE TERM OF A PATENT

Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

In re Patent No. 4,949,718
Issued to: Robert S. Neuwirth and Lee R. Bolduc
Issue Date: August 21, 1990
For: INTRAUTERINE CAUTERIZING APPARATUS

Docket Ref: Gynelab718

Dear Sir:

We are transmitting herewith the attached:

X Application Papers for Extension of the Term of a Patent (original and 4 certified* copies) including photocopies of:

- X Exhibit A-ThermaChoice™ Uterine Balloon Therapy System (1) Patient Information Brochure; (2) Catheter Instructions for Use; and (3) UBT System Operating Manual;
- X Exhibit B-Patent No. 4,949,718 issued to Neuwirth et al on August 21, 1990;
- X Exhibit C-Notice of Intent to Issue Reexamination Certificate, mailed September 30, 1997;
- X Exhibit D-Description of activities undertaken by licensee during the applicable regulatory period;
- X Exhibit E-Power of Attorney and Certificate under 37 CFR 3.73(b); and
- X Exhibit F-Authorization of the Pre-Marketing Approval Holder-Gynecare, Inc./Ethicon, Inc.

X *Rule 740(16) Certification of Duplicate of Application for Extension of the Term of a Patent (attached to 4 copies).

X Stamped return addressed postcard.

X A check in the amount of $1120.00 (Extension of Term of Patent-37 CFR 1.20(j)(1).

X Please charge any deficiency or credit any overpayment in fees to Deposit Account No. 15-0508. A duplicate of this transmittal is enclosed.

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01 FC:111 1120.00 OP

Date: February 6, 1998

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CERTIFICATION UNDER 37 C.F.R. 1.10

EM322714829US
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By: Talivaldis Cepuritis

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Cederic Rodgers
Name of Person Mailing Application

Cederic Rodgers
(Signature of Person Mailing Application)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Robert S. Neuwirth and Lee R. Bolduc

Assignee: Gynelab Products, Inc.

Patent No.: 4,949,718

Licensee: Gynecare, Inc./Ethicon, Inc.

Issue Date: August 21, 1990

For: INTRAUTERINE CAUTERIZING APPARATUS

APPLICATION FOR EXTENSION OF THE TERM OF A PATENT

Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

Docket Ref.: Gynelab 718

Dear Sir:

Pursuant to 35 U.S.C. §156, extension of the term of the above-identified United States patent is respectfully requested. Pursuant to the guidelines published by the Commissioner, the following information is being submitted.

(1) A complete identification of the approved ThermaChoice™ Uterine Balloon Therapy (UBT) System is set forth in attached collective Exhibit A in the photocopies of the Patient Information Brochure (Exhibit A(1)); the Catheter

Instructions for Use (Exhibit A(2)); and the UBT System Operating Manual (Exhibit A(3)) of owner's exclusive licensee, Gynecare, Inc./Ethicon, Inc. describing and illustrating the product.

(2) The regulatory review occurred under Title 21, United States Code, the Federal Food, Drug and Cosmetic Act, as amended 1976, §515(d)(1)(B)(ii) [21 U.S.C. §360e(d)(1)(B)(ii)] and §520(e) [21 U.S.C. §360j(e)].

(3) The product received permission for commercial marketing by owner's licensee, Gynecare, Inc./Ethicon, Inc. on December 12, 1997, under the provisions of the Federal Food, Drug and Cosmetic Act as administered by the Food and Drug Administration (FDA) under which the applicable regulatory review period occurred.

(4) This is not a human drug product, therefore no ingredients are described.

(5) This application is being submitted within the sixty day period permitted for submission, the date of the last day on which the application could be submitted being February 9, 1998.

(6) United States patent No. 4,949,718 is the patent for which an extension is being sought. The patent, which is set to expire on September 9, 2008, was issued to Robert S. Neuwirth and Lee R. Bolduc on August 21, 1990, and is owned by the applicant, Gynelab Products, Inc.

(7) Enclosed as Exhibit B is a copy of patent No. 4,949,718 for which an extension is being sought.

(8) Patent No. 4,949,718 is the subject of the following two pending Reexaminations but no Reexamination Certificate has issued:

a. Reexamination No. 90/004/457 filed November 12, 1996 in which a Notice of Intent to Issue Reexamination Certificate was mailed September 30, 1997, a copy of which is attached as Exhibit C; and

b. Reexamination No. 90/004,724, filed August 14, 1997.

(9) Patent No. 4,949,718 claims the approved ThermaChoice™ Uterine Balloon Therapy (UBT) System. Claims 1-6 and 9-20 of U.S. Patent No. 4,949,718 and claims 1-6 and 9-20 as amended in Reexamination No. 90/004/457 are applicable to and read on the approved ThermaChoice™ Uterine Balloon Therapy System as indicated below.

A. U.S. Patent No. 4,949,718

1. An apparatus for effecting necrosis of an uterine endometrium comprising:	The UBT System is a device designed to ablate uterine tissue by thermal energy for effecting necrosis of the uterine endometrium. See Exhibit A(1), section "What is ThermaChoice™ Uterine Balloon Therapy"; and Exhibits A(2) and A(3), page 1, "Device Description" section.
a catheter having a proximal end and a distal end;	The UBT System has a catheter having a proximal and distal end. See description of catheter in Exhibit A(1) section "How does ThermaChoice work?"; and the graphic representation of the catheter on pages 2 and 8 of Exhibit A(2); and pages 2 and 9 of Exhibit A(3).
a distendable bladder means attached to said proximal end for insertion into and distending the uterus;	The UBT System has a distendable balloon bladder attached to the catheter end which is inserted into the uterus. See the description of the soft flexible balloon catheter and the pictorial depiction of its insertion in the uterus in Exhibit A(1); and the diagram of the balloon catheter unit (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
inflating means connected to said distal end for	The UBT System has an inflating syringe connected to

introducing an inflation medium into said bladder;	the end of the catheter opposite the balloon bladder for introducing sterile fluid (5% dextrose in water) into the balloon for inflation. See Exhibit A(1) section "How does ThermaChoice work?"; and the diagrams showing the connection of the syringe to the balloon catheter (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
heating means for heating said inflation medium to a temperature sufficient to effect tissue necrosis positioned internal to said bladder; and	The UBT System has a heater for heating the sterile fluid in the inflated balloon. See the description of the heated fluid in Exhibit A(1), section "How does ThermaChoice work?"; the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the description of the activation of the heater on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
control means connected to said distal end for regulating the inflating and heating of said bladder.	The UBT System has a controller attached to the balloon catheter for regulating the inflation and heating of the balloon bladder. The regulation of the inflation and fluid temperature is described in Exhibit A(1) section "How does ThermaChoice work?"; and by the discussion of the pressure line and heater control function of the controller (GC-EAS) in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3).

2. The apparatus of claim 1, wherein said catheter is comprised of rigid tubing at the proximal end of said bladder, and flexible tubing extending through said rigid tubing from said control means to said bladder.	See discussion of claim 1 above and the description of the assembly of the balloon catheter (GC-EAC) and Umbilical Cable (GC-EAU) on pages 2 and 8 of Exhibit A(2) and on pages 2 and 9 of Exhibit A(3).
3. The apparatus of claim 2, wherein said inflating means comprises a pump means connected to said flexible tubing for pumping said inflation medium through said flexible tubing so as to inflate said bladder.	See discussion of claim 2 above and the description of the syringe and its function for pumping the inflation fluid to inflate the balloon catheter on pages 2 and 8-10 of Exhibit A(2) and on pages 2 and 9-11 of Exhibit A(3).
4. The apparatus of claim 3, wherein said pumping means comprises a hypodermic barrel.	See discussion of claim 3 above and description of the hypodermic pump barrel on pages 2 and 8 of Exhibit A(2) and on pages 2 and 9 of Exhibit A(3).
5. The apparatus of claim 4, wherein said hypodermic barrel is connected to said flexible tubing by a three-way valve.	See discussion of claim 4 above and the connection of the hypodermic barrel to the trumpet valve, which is the functional equivalent of the three-way valve, shown in the cited Exhibits.
6. The apparatus of claim 3, wherein said fluid is non-circulating.	See discussion of claim 3 above and the description of how the fluid is retained in static mode in the balloon during treatment until withdrawn in Exhibit A(1) section "How does ThermaChoice work?"; and sections 3-5 of the instructions for the introduction of fluid into the balloon before treatment, static retention of fluid during treatment and withdrawal of fluid after treatment in Exhibit A(2), pages 9-11 and Exhibit A(3), 10-12.

9. The apparatus of claim 2, further comprising a positioning means for positioning said distendable bladder in the uterus.	See discussion of claim 2 above and the reference to the "Depth, Sound Measurement (cm)" in the diagram on page 2 of Exhibit A(2) and A(3) and paragraph 3.5 of the instructions in Exhibit A(2), page 9 and in Exhibit A(3), page 10 where the positioning of the balloon in the uterus is described.
10. The apparatus of claim 9, wherein said positioning means comprises scale gradations on said catheter for indicating depth of insertion of said distendable bladder into the uterus.	See discussion of claim 9 above and the references to the depth markings in paragraph 3.5 of the instructions in Exhibit A(2), page 9 and in Exhibit A(3), page 10 where the positioning of the balloon in the uterus is described.
11. The apparatus of claim 1, further comprising means for disengaging said catheter from said control means so that the applicator and the control means may be separated.	See discussion of claim 1 above, the "Device Description" section on page 1 of Exhibits A(2) and A(3) setting out the components of the UBT System device; and paragraph 1, "SET-UP" in the directions for use of the balloon catheter (i.e., applicator) and its attachment to the controller (GC-EAS) on page 7 of Exhibit A(2) and page 8 of Exhibit A(3).
12. The apparatus of claim 1, wherein said distendable bladder is capable of resisting an internal pressure of at least 300mmHg without rupturing and a temperature of at least 250° Fahrenheit without carbonizing.	See discussion of Exhibits in claim 1 above referring to the distendable balloon catheter. The balloon is natural rubber latex, which meets the pressure and temperature requirements.
13. The apparatus of claim 12, wherein said bladder is selected from the group comprising latex rubber.	See discussion of claim 12 above, and the "Caution" statement in Exhibit A(1) concerning latex allergy which also appears on page 1 of Exhibits A(2) and A(3).

14. The apparatus of claim 1, wherein said control means comprises:	See discussion in claim 1 above of the UBT System and of the controller (GC-EAS) in collective Exhibit A.
volume control means;	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2, and in the instructions for controlling the volume on pages 9-10 of Exhibit A(2) and pages 10-11 of Exhibit A(3).
temperature control means	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and in the instructions for controlling the temperature on pages 10-11 of Exhibit A(2) and pages 11-12 of Exhibit A(3).
pressure control means; and	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and in the instructions for controlling the pressure on pages 9-10 of Exhibit A(2) and pages 10-11 of Exhibit A(3).
time control means.	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and the description of the timer in the instructions for use on pages 10-11 of

	Exhibit A(2) and pages 11-12 of Exhibit A(3).
15. The apparatus of claim 14, wherein said temperature control means comprises a thermocouple for measuring the temperature of said inflation medium fixed to the proximal end of said catheter and positioned internal to said bladder;	See discussion of claim 14 above. The temperature of the fluid inside the balloon is controlled automatically as described on pages 2, and 10-11 of Exhibit A(2) and on pages 2, and 11-12 of Exhibit A(3).
said thermocouple connected to said control means via a second electrical lead.	See description of the umbilical cable assembly on pages 2 of both Exhibit A(2) and A(3) and its connection to the controller.
16. The apparatus of claim 14, wherein said pressure control means comprises;	See discussion of claim 14 above, and the description of the connection of the pressure line to the controller on pages 2 of both Exhibit A(2) and A(3).
a pressure sensor connected to said flexible tubing;	See the description of the connection of the pressure line on page 2 and 9 of Exhibit A(2) and page 2 and 10 of Exhibit A(3) to the holder for the umbilical cable.
said pressure sensor connected to a pressure display means for displaying and regulating the pressure of said inflating means.	The controller panel has a pressure display window as shown in the description of the controller panel on pages 2 and 12-14 of Exhibit A(3).
17. The apparatus of claim 14, wherein said time control means comprises a clock.	See discussion of claim 14 above and the description of the time display window in the description of the controller panel on pages 2 and 12-14 of Exhibit A(3).
18. The apparatus of claim 17, wherein said clock is programmable and connected to said temperature control means.	See discussion of claim 17 above, and the description of the automatic features of the timer and temperature control by the controller in Exhibit

	A(2), pages 10-11 and Exhibit A(3) pages 11-12.
19. An apparatus for effecting necrosis of a tissue lining in a body cavity comprising:	The UBT System is a device designed for effecting necrosis of the uterine lining. See the section "What is ThermaChoice™ Uterine Balloon Therapy" in Exhibit A(1); and Exhibits A(2) and A(3), page 1 "Device Description" section.
a catheter comprising a length of flexible tubing having a distal end and a proximal end;	The UBT System uses a balloon catheter (GC-EAC) and umbilical cable assembly (GC-EAU), which is shown by the graphic representation on pages 2 and 8 of Exhibit A(2); and pages 2 and 9 of Exhibit A(3).
a bladder means for insertion into and distending the body cavity attached to a proximal end;	The UBT System has a distendable balloon bladder attached to the catheter end which is inserted into the uterus. See the description of the soft flexible balloon catheter and the pictorial depiction of its insertion in the uterus in Exhibit A(1); and the diagram of the balloon catheter unit (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
inflating means connected to said distal end for introducing an inflation medium through said flexible tubing and into said bladder;	The UBT System has an inflating syringe connected to the end of the catheter opposite the balloon bladder for introducing sterile fluid (5% dextrose in water) into the balloon for inflation. See Exhibit A(1) section "How does ThermaChoice work?"; and the diagrams showing the position of the syringe in the assembly of the balloon catheter on pages 2 and 8 of

	Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
a heating means for heating said inflation medium to a temperature sufficient to effect tissue necrosis positioned internal to said bladder; and	The UBT System has a heater for heating the sterile fluid in the inflated balloon. See the description of the heated fluid in Exhibit A(1), section "How does ThermaChoice work?"; the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3); and the description of the activation of the heater on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
control means connected to said distal end for regulating inflation and heating of said bladder.	The UBT System has a controller attached to the balloon catheter for regulating the inflation and heating of the balloon bladder. The regulation of the fluid temperature in the balloon is described in Exhibit A(1) section "How does ThermaChoice work?"; and by the discussion of the pressure line and heater control function of the controller (GC-EAS) is in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3).
20. The apparatus of claim 19 further comprising a thermocouple for measuring the temperature of said inflation medium positioned internal to said bladder and connected to said control means via an electrical lead.	See discussion of claim 19 above. The temperature of the fluid inside the balloon is controlled automatically as described on pages 2, and 10-11 of Exhibit A(2) and on pages 2 and 11-12 of Exhibit A(3) and the description of the umbilical cable assembly which is connected to the controller is on page 2 of Exhibits A(2) and A(3).

B. The pending claims as amended, and indicated as allowed, in Reexamination No. 90/004/457

1. An apparatus for effecting necrosis of human uterine endometrium comprising:	The UBT System is a device designed to ablate uterine tissue by thermal energy for effecting necrosis of the uterine endometrium. See Exhibit A(1), section "What is the ThermaChoice™ Uterine Balloon Therapy"; and Exhibits A(2) and A(3), page 1, "Device Description" section.
a catheter for insertion into human uterus via the cervical canal thereof, said catheter terminating in a rigid, axially closed proximal end portion and having an open distal end;	The UBT System has a catheter that is axially closed at one end portion and open at the opposite end. See pictorial representation of the balloon catheter inserted in the uterus via the cervical canal in Exhibit A(1) section "How does ThermaChoice work?"; and the graphic representation of the balloon catheter (GC-EAC) on pages 2 and 8 of Exhibit A(2); and pages 2 and 9 of Exhibit A(3).
a distendable bladder defining an enclosure attached to said proximal end portion for insertion into and distending the uterus; and for contacting substantially all of said endometrium; said distendable bladder projecting axially beyond the proximal end of the catheter when distended;	The UBT System has a distendable balloon bladder attached to the catheter end which is inserted into the uterus. See the description of the soft flexible balloon catheter and the pictorial depiction of its insertion in the uterus in Exhibit A(1); and the diagram of the balloon catheter unit (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
inflating means connected to said distal end for introducing an inflation medium into said bladder;	The UBT System has an inflating syringe connected to the end of the catheter opposite the balloon bladder for introducing sterile fluid (5% dextrose in water) into

	the balloon. See Exhibit A(1) section "How does ThermaChoice work?"; and the diagrams showing the connection of the syringe to the balloon catheter unit (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
heating means for heating said inflation medium to a temperature sufficient to effect tissue necrosis positioned internal to said bladder; and	The UBT System has a heater for heating the sterile fluid in the balloon bladder. See the description of the heated fluid in Exhibit A(1), section "How does ThermaChoice work?"; the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the description of the activation of the heater on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
control means connected to said distal end for regulating the inflating and heating of said bladder.	The UBT System has a controller attached to the balloon catheter for regulating the inflation and heating of the balloon bladder. The regulation of the inflation and fluid temperature is described in Exhibit A(1) section "How does ThermaChoice work?"; and by the discussion of the pressure line and heater control function of the controller (GC-EAS) in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3).
2. The apparatus of claim 1, wherein said catheter is comprised of rigid tubing at the proximal end of said bladder, and flexible tubing	See discussion of claim 1 above and the description of the assembly of the balloon catheter (GC-EAC) and Umbilical Cable (GC-EAU) on

extending through said rigid tubing from said control means to said bladder.	pages 2 and 8 of Exhibit A(2) and on pages 2 and 9 of Exhibit A(3).
3. The apparatus of claim 2, wherein said inflating means comprises a pump means connected to said flexible tubing for pumping said inflation medium through said flexible tubing so as to inflate said bladder.	See discussion of claim 2 above and the description of the syringe and its function for pumping the inflation fluid to inflate the balloon catheter on pages 2 and 8-10 of Exhibit A(2) and on pages 2 and 9-11 of Exhibit A(3).
4. The apparatus of claim 3, wherein said pumping means comprises a hypodermic barrel.	See discussion of claim 3 above and description of the hypodermic pump barrel on pages 2 and 8 of Exhibit A(2) and on pages 2 and 9 of Exhibit A(3).
5. The apparatus of claim 4, wherein said hypodermic barrel is connected to said flexible tubing by a three-way valve.	See discussion of claim 4 above and the connection of the hypodermic barrel to the trumpet valve, which is the functional equivalent of the three-way valve, shown in the cited Exhibits.
6. The apparatus of claim 3, wherein said fluid is non-circulating.	See discussion of claim 3 above and the description of how the fluid is retained in static mode in the balloon during treatment until withdrawn in Exhibit A(1) section "How does ThermaChoice work?"; and sections 3-5 of the instructions for the introduction of fluid into the balloon before treatment, static retention of fluid during treatment and withdrawal of fluid after treatment in Exhibit A(2), pages 9-11 and Exhibit A(3), 10-12.
9. The apparatus of claim 2, further comprising a positioning means for positioning said distendable bladder in the uterus.	See discussion of claim 2 above and the reference to the "Depth, Sound Measurement (cm)" in the diagram on page 2 of Exhibit A(2) and A(3) and paragraph 3.5 of the

	instructions in Exhibit A(2), page 9 and in Exhibit A(3), page 10 where the positioning of the balloon in the uterus is described.
10. The apparatus of claim 9, wherein said positioning means comprises scale gradations on said catheter for indicating depth of insertion of said distendable bladder into the uterus.	See discussion of claim 9 above and the references to the depth markings in paragraph 3.5 of the instructions in Exhibit A(2), page 9 and in Exhibit A(3), page 10 where the positioning of the balloon in the uterus is described.
11. The apparatus of claim 1, further comprising means for disengaging said catheter from said control means so that the applicator and the control means may be separated.	See discussion of claim 1 above, the "Device Description" section on page 1 of Exhibits A(2) and A(3) setting out the components of the UBT System device; paragraph 1, "SET-UP" in the directions for use of the balloon catheter (i.e., applicator) and its attachment to the controller (GC-EAS) on page 7 of Exhibit A(2) and page 8 of Exhibit A(3).
12. The apparatus of claim 1, wherein said distendable bladder is capable of resisting an internal pressure of at least 300mmHg without rupturing and a temperature of at least 250° Fahrenheit without carbonizing.	See discussion of Exhibits in claim 1 above referring to the distendable balloon catheter. The balloon is natural rubber latex, which meets the pressure and temperature requirements.
13. The apparatus of claim 12, wherein said bladder is selected from the group comprising latex rubber.	See discussion of claim 2 above, and the "Caution" statement in Exhibit A(1) concerning latex allergy which also appears on page 1 of Exhibits A(2) and A(3).
14. The apparatus of claim 1, wherein said control means comprises:	See discussion in claim 1 above of the UBT System and of the controller (GC-EAS) in collective Exhibit A.
volume control means;	See discussion of controller

	(GC-EAS) in claim 1 above and the description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and in the instructions for controlling the volume on pages 9-10 of Exhibit A(2) and pages 10-11 of Exhibit A(3).
temperature control means	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and in the instructions for controlling the temperature on pages 10-11 of Exhibit A(2) and pages 11-12 of Exhibit A(3).
pressure control means; and	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and in the instructions for controlling the pressure on pages 9-10 of Exhibit A(2) and pages 10-11 of Exhibit A(3).
time control means.	See description of the assembly features of the controller panel in Exhibit A(2) and A(3) with the balloon catheter (GC-EAC) and umbilical cable (GC-EAU) on page 2 and the description of the timer in the instructions for use on pages 10-11 of Exhibit A(2) and pages 11-12 of Exhibit A(3).
15. The apparatus of claim 14, wherein said temperature control means	See discussion of claim 14 above. The temperature of the fluid inside the balloon is

comprises a thermocouple for measuring the temperature of said inflation medium fixed to the proximal end of said catheter and positioned internal to said bladder;	controlled automatically as described on pages 2, and 10-11 of Exhibit A(2) and pages 2 and 11-12 of Exhibit A(3).
said thermocouple connected to said control means via a second electrical lead.	See description of the umbilical cable assembly on pages 2 of both Exhibit A(2) and A(3) which is connected to the controller.
16. The apparatus of claim 14, wherein said pressure control means comprises;	See discussion of claim 14 above, and the description of the connection of the pressure line to the controller on pages 2 of both Exhibit A(2) and A(3).
a pressure sensor connected to said flexible tubing;	See the description of the connection of the pressure line on page 2 and 9 of Exhibit A(2) and page 2 and 10 of Exhibit A(3) to the holder for the umbilical cable.
said pressure sensor connected to a pressure display means for displaying and regulating the pressure of said inflating means.	The controller panel has a pressure display window as shown in the description of the controller panel on pages 2 and 12-14 of Exhibit A(3).
17. The apparatus of claim 14, wherein said time control means comprises a clock.	See discussion of claim 14 above and the description of the time display window in the description of the controller panel on pages 2 and 12-14 of Exhibit A(3).
18. The apparatus of claim 17, wherein said clock is programmable and connected to said temperature control means.	See discussion of claim 17 above, and the description of the automatic features of the timer and temperature control by the controller in Exhibit A(2), pages 10-11 and Exhibit A(3) pages 11-12.
19. An apparatus for effecting necrosis of human uterine endometrium comprising:	The UBT System is a device designed for effecting necrosis of the uterine lining. See the section "What

	is ThermaChoice™ Uterine Balloon Therapy" in Exhibit A(1); and Exhibits A(2) and A(3), page 1 "Device Description" section.
a catheter for insertion into human uterus comprising a length of flexible tubing having an open distal end and an axially closed, rigid proximal end portion;	The UBT System uses a balloon catheter (GC-EAC) and umbilical cable assembly (GC-EAU), which is shown by the graphic representation on pages 2 and 8 of Exhibit A(2); and pages 2 and 9 of Exhibit A(3).
a bladder means for insertion into and distending the uterus and attached to the proximal end portion, said bladder means extending beyond the proximal ed of the catheter when distended;	The UBT System has a distendable balloon bladder attached to the catheter end which is inserted into the uterus. See the description of the soft flexible balloon catheter and the pictorial depiction of its insertion in the uterus in Exhibit A(1); and the diagram of the balloon catheter unit (GC-EAC) on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
inflating means connected to said distal end for introducing an inflation medium through said flexible tubing and into said bladder;	The UBT System has an inflating syringe connected to the end of the catheter opposite the balloon bladder for introducing sterile fluid (5% dextrose in water) into the balloon for inflation. See Exhibit A(1) section "How does ThermaChoice work?"; and the diagrams showing the position of the syringe in the assembly of the balloon catheter on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3).
a heating means for heating said inflation medium to a temperature sufficient to effect tissue necrosis positioned internal to said bladder; and	The UBT System has a heater for heating the sterile fluid in the inflated balloon. See the description of the heated fluid in Exhibit A(1), section "How does ThermaChoice work?";

	the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3); and the description of the activation of the heater on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
control means connected to said distal end for regulating inflation and heating of said bladder.	The UBT System has a controller attached to the balloon catheter for regulating the inflation and heating of the balloon bladder. The regulation of the fluid temperature in the balloon is described in Exhibit A(1) section "How does ThermaChoice work?"; and by the discussion of the pressure line and heater control function of the controller (GC-EAS) is in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3); and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3).
20. The apparatus of claim 19 further comprising a thermocouple for measuring the temperature of said inflation medium positioned internal to said bladder and connected to said control means via an electrical lead.	See discussion of claim 19 above. The temperature of the fluid inside the balloon is controlled automatically as described on pages 2, and 10-11 of Exhibit A(2) and on pages 2, and 11-12 of Exhibit A(3) and the description of the umbilical cable assembly which is connected to the controller is also on page 2 of Exhibits A(2) and A(3).

(10) The relevant dates and information necessary in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period pursuant to 35 U.S.C. §156(g) are set forth as follows, references being made to 35 U.S.C. §156(g)(3)(B):

i. Effective date of IDE No. G940155: November 30, 1994.

ii. Clinical investigation on humans first begun: January 2, 1996.

iii. Premarket approval application initially submitted: June 16, 1997.

iii. PMA No. P970021 granted: December 12, 1997.

All additional relevant dates are set forth in attached Exhibit D.

(11) A brief description of the activities undertaken by the exclusive licensee of applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is set forth in attached Exhibit D.

A description of the clinical use of the ThermaChoice™ Uterine Balloon Therapy System is set forth in Exhibit A(2), pages 4-7 and Exhibit A(3), pages 6-8.

(12) In the opinion of the applicant, the patent is eligible for the extension until November 29, 2009.

The 446 day term of extension is computed in accordance with 37 CFR § 1.777(d)(2). This date is earlier than the term extension computed by adding 14 years to the date of the approval of the premarketing application (i.e., calculated from December 12, 1997) under 37 CFR § 1.777(d)(3) or the five year maximum period added to the original expiration date of the patent (i.e., calculated as 20 years from filing date of September 9, 1988) under 37 CFR § 1.777(d)(5)(i).

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee under 37 CFR 1.20(j)(1) for receiving and acting upon the application for extension in the amount of $1,120.00 is concurrently enclosed.

(15) All inquiries and correspondence relating to the application for patent term extension are to be directed to the undersigned pursuant to:

a. Power of Attorney from Gynelab Products, Inc., the Owner Applicant, to Talivaldis Cepuritis et al, to prosecute this application and Assignee Certification under 37 CFR §3.73 attached as Exhibit E; and

b. Authorization of the Pre-Marketing Approval Holder, Gynecare, Inc./Ethicon, Inc., the exclusive licensee of Gynelab Products, Inc. attached as Exhibit F. Gynecare, Inc. was acquired by Ethicon, Inc. in November, 1997 and is a wholly owned subsidiary of Ethicon, Inc.

(16) A duplicate of the application papers (including Exhibits), certified as such, is submitted herewith in quadruplicate.

The undersigned declares that he:

1. is a patent attorney authorized to practice before the Patent and Trademark Office and has a power of attorney, submitted herewith as Exhibit E, authorizing him to act on behalf of the Owner Applicant in patent matters;

2. has reviewed and understands the contents of this application being submitted pursuant to 37 CFR §1.740;

3. believes Patent No. 4,949,718 is subject to extension pursuant to 37 CFR §1.710, because it claims a medical device subject to regulation under the Federal Food, Drug and Cosmetic Act;

4. believes an extension of the length claimed is fully justified under 35 U.S.C. §156 and the applicable regulations; and

5. believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 CFR §1.720 because:

a. the patent claims an Intrauterine Cauterizing Apparatus which is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act;

b. the term of the patent has never been previously extended;

c. this application for extension is being appropriately submitted pursuant to the Rules;

d. the product has been subjected to a regulatory review period as defined in 35 U.S.C. §156(g) and by the Secretary of Health and Human Services before its commercial marketing or use;

e. the product has received permission for commercial marketing or use and the application is being submitted within the sixty day period beginning on the date the product first received permission for commercial marketing under the provision of law

under which the applicable regulatory review period occurred;

f. the term of the patent has not expired before the submission of this application; and

g. no other patent has been extended for the same regulatory review period for the product.

The undersigned hereby declares further that all statements made herein of his own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any extension of patent term issuing thereon.

Respectfully submitted,

Date: February 6, 1998

By: _____
Talivaldis Cepuritis
Reg. No. 20,818

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